

REMARKS/ARGUMENTS

Claims 1-15 are pending in the instant application. Claims 1-15 stand rejected.

Claims 1-15 stand rejected under 35 U.S.C. §112, first paragraph for lacking enablement.

Claims 1-15 stand rejected under 35 U.S.C. §112, second paragraph for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention.

Claims 1-15 stand rejected under stand rejected under 35 U.S.C. §103 as being unpatentable in view of United States Patent No. 4,994,013 to Suthanthiran et al. Claims 1-15 stand rejected under stand rejected under 35 U.S.C. §103 as being unpatentable in view of United States Patent No. 5,713,828 to Coniglione. The Examiner has also objected to the specification for lacking continuing data in the first line thereof and for lacking an abstract.

In the interests of more quickly furthering prosecution, the application has been amended without prejudice to subsequently filing a continuation application directed towards broader claims. Claim 1, 8, 13, and 14 have been amended. Claims 2, 3, 11, 12, and 15 have been cancelled without prejudice. None of the amendments constitute new matter in contravention of the requirements of 35 U.S.C. §132. Reconsideration is respectfully requested.

The Examiner has objected to the specification for lacking continuing data in the first line thereof and for lacking an abstract. These objections are obviated by the amendments to the specification hereinabove. Reconsideration and withdrawal of the objections are respectfully requested.

Appl. No. 10/009,576
Amdt. Dated August 6, 2004
Reply to Office action of Feb. 9, 2004

Claims 1-15 stand rejected under 35 U.S.C. §112, first paragraph for lacking enablement. This rejection is respectfully traversed.

The Examiner contends that the specification ‘does not reasonably provide enablement for all substrates and iodine containing compounds’. However, such a statement does not accurately recite the claim scope of the instant invention. The present invention does not claim all substrates and all iodine containing compounds, rather the “substrates” are limited to those which are substantially non-radiation attenuating and the “iodine containing compounds” are defined at page 6, lines 4-7 as including “any compound containing covalently bonded iodine where the iodine is bonded to at least one other atom which is not a halogen”. Applicants respectfully submit that it is well-known whether a potential substrate will have an attenuating effect on radiation or not. Furthermore, one of ordinary skill in the art will understand whether a particular iodide or iodine containing compound may be adsorbed onto the substate without undue experimentation..

The key to analyzing an “undue experimentation” attack on the enablement of a patent . . . is in determining what is “undue”, because some trial and error is permissible. W.L. Gore & Associates v. Garlock, Inc., 220 U.S.P.Q 303 (Fed. Cir. 1993). The need for a minimum amount of experimentation is not fatal if the skill in the art is such that the disclosure enables one to make the invention. Martin, Aebi, and Ebner v. Johnson, 172 U.S.P.Q. 391 (C.C.P.A. 1972). “The key word is ‘undue’, not ‘experimentation’ . . . The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine or if the specification in question provides a reasonable amount of

Appl. No. 10/009,576
Amtd. Dated August 6, 2004
Reply to Office action of Feb. 9, 2004

guidance with respect to the direction in which the experimentation should proceed.” In re Wands, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). Applicants respectfully submit that the present invention enables the present invention by clearly stating and demonstrating what the invention is, as well as providing guidance with respect to how any experimentation should proceed. It would at most only require a minimum amount of routine experimentation for one of ordinary skill in the art to determine whether an iodide or iodine containing compound is adsorbed onto a generally non-radiation attenuating substrate.

In view of these remarks, Applicants respectfully submit that claims 1-15 do not require undue experimentation and that the rejection under §112, first paragraph is improper. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-15 stand rejected under 35 U.S.C. §112, second paragraph for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. This rejection is respectfully traversed.

First, the Examiner states that the claims are ambiguous because one cannot readily ascertain what is claimed as the claims read on “a multitude of iodine-containing compounds, non-radiation attenuating substrates, and brachytherapy sources.” In response, Applicants respectfully submit that the Examiner is mischaracterizing the invention as the claims recite a brachytherapy source comprising . . . the iodine compounds adsorbed on the substrates and not a brachytherapy source in addition to the iodine compounds and substrates. Thus there is no need to search ‘brachytherapy sources’ generally. Additionally, as noted hereinabove, the

Appl. No. 10/009,576
Amdt. Dated August 6, 2004
Reply to Office action of Feb. 9, 2004

specification defines the term “iodine containing compounds” and is clear regarding the non-radiation attenuating substrates.

The Examiner further takes issues with dependent claims 7 and 8 for what is considered to be multitudes of possibilities. Applicants respectfully submit that as claims 7 and 8 further limit the elements of independent claim 1, both are properly defining the instant invention in greater detail.

The Examiner concludes by requesting the Applicants to clarify the claims “in order that one may determine what is being claimed and conduct a thorough search”. Applicants respectfully submit that claim 1 distinctly claims the present invention as described in the specification. Moreover, even assuming *arguendo* that the dependent claims include too many possible components, their being in dependent claims should make the job of searching for prior art easier, not more difficult.

Applicants respectfully submit that a search for a brachytherapy source as presently claimed should not be overly burdensome. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-15 stand rejected under stand rejected under 35 U.S.C. §103 as being unpatentable in view of United States Patent No. 4,994,013 to Suthanthiran et al. This rejection is respectfully traversed.

Appl. No. 10/009,576
Amdt. Dated August 6, 2004
Reply to Office action of Feb. 9, 2004

Suthanthiran discloses a metallic X-ray detectable marker rod coated with a radioactive-absorbing material in a binder wherein a radioactive material is absorbed.

The present invention, conversely, provides a radioactive isotope of iodine in the form of either idodide or an iodine-containing compound. The isotope is adsorbed on the surface of a substantially non-radiation attenuating substrate. The isotope and substrate are sealed within a biocompatible echogenic container.

Suthanthiran fails to disclose either a biocompatible echogenic container or an isotope adsorbed by a substrate, both of which are claimed by the present invention. Moreover, there is no teaching or suggestion in Suthanthiran to modify its disclosed brachytherapy source so as to correct these defects. To support obviousness, the proper test is whether the reference, taken as a whole, would suggest the invention to one of ordinary skill in the art. Milliken Research Corp. v. Dan River, Inc., 222 U.S.P.Q 571 (Fed. Cir. 1984). Applicants respectfully submit that as Suthanthiran is silent about adsorbing an isotope into a substrate and sealing both within a biocompatible echogenic container, Suthanthiran fails to disclose, teach, or suggest the present invention. Thus the present invention is patentably distinct thereover. Reconsideration and withdrawal of the rejection are respectfully requested. .

Appl. No. 10/009,576
Amdt. Dated August 6, 2004
Reply to Office action of Feb. 9, 2004

Claims 1-15 stand rejected under stand rejected under 35 U.S.C. §103 as being unpatentable in view of United States Patent No. 5,713,828 to Coniglione. This rejection is respectfully traversed.

Coniglione discloses an apparatus for brachytherapy in which a radioisotope is coated on the outer surface of an inner tube. The inner tube is sealed within an outer tube so as to form a tubular brachytherapy device.

Coniglione, however, fails to disclose, teach, or suggest sealing a radioactive isotope adsorbed on a substrate within a biocompatible echogenic container. It is well settled that a *prima facie* case of obviousness is established when the teaching from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. In re Rijckaert, 28 U.S.P.Q.2d 1955 (Fed. Cir. 1993). Applicants respectfully submit that as Coniglione fails to suggest sealing a radioactive isotope adsorbed on a substrate within a biocompatible echogenic container, a *prima facie* case of obviousness is not established by reference thereto. As a result, Applicants respectfully submit that the instant invention is patentably distinct thereover. Reconsideration and withdrawal of the rejection is respectfully requested.

In view of the amendments and remarks hereinabove, Applicants respectfully submit that the instant application, including claims 1, 4-10, and 13-14, is in condition for allowance. Favorable action thereon is respectfully requested.

Appl. No. 10/009,576
Amdt. Dated August 6, 2004
Reply to Office action of Feb. 9, 2004

Any questions the Examiner may have with respect to the instant application may be directed to Applicants' undersigned counsel at the telephone number below.

Respectfully submitted,



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